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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,255	07/10/2003	Reid M. Rubsamen	FLOW-019	3925

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EXAMINER	
KATAKAM, SUDHAKAR	
ART UNIT	**PAPER NUMBER**
1621	

DATE MAILED: 10/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/618,255	RUBSAMEN, REID M.	
	Examiner	Art Unit	
	Sudhakar Katakam	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *March 7, 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-36 are rejected under 35 U.S.C 103(a) as being unpatentable over US 6,238,491 and US Pub.No. 2002/0165608 in view of US 6,228,398 and Ansel et al (Pharmaceutical dosage forms and drug delivery systems, 7th edition).

Davidson et al (US Pat# 6,238,491) teaches manufacture of a variety of medical implants and devices, which includes orthopedic implants, specifically bone fracture plates, screws, compression hip plates and lag screws, intramedulary rods, staples, and various internal and external tissue fixation devices (col. 10, lines 51-63). It anticipates a portion of the surface of the implant can be conversion surface hardened and /or coated. Such coatings can include, but are not limited, antibiotics, pro- or anti-thrombogenic agents, anti-inflammatory agents, morphogenic proteins, morphogenic peptides, growth factors, or stem cells (col. 11, lines 5-12). **Llanos et al (Pub. No. US 2002/0165608)** teaches local drug medical devices are utilized to deliver therapeutic dosages of drugs, agents or compounds directly to the site where needed. The method comprises releasable affixing one or more agents in therapeutic dosages to the medical device, treating one of the medical device or the delivery device with a material for

preventing the one or more agents from separating from the medical device during delivery and implantation of the medical device at the treatment site, and loading the medical device into a delivery device ([0022] and [0023]). They anticipate surgical devices, bone pins, screws, plates etc., could provide enhanced patient benefit using this drug-device combination approach ([0040]).

Thus, medical implant or device of Davidson et al and Llanos et al read on the instant claimed a solid component having bound to a surface and hence Davidson or Llanos anticipates instant claims 1 and 36 and its depend claims.

Devane et al (US Pat# 6,228,398) teaches a multiparticulate (i.e., a plurality of discrete, or aggregated, particles, pellets, beads, granules or mixtures thereof irrespective of their size, shape or morphology) modified release composition that is operation delivers an active ingredient in a pulsed or bimodal manner (col 6 and col 7). So, this multiparticulate modified release composition having a first component comprising a first population of active ingredient containing particles and a second compound comprising a second population of active ingredient containing particles (col. 4). Devene et al also teaches that multiparticulate modified release composition of the invention may have more than two active ingredient containing compounds. Examples of active ingredients include analgesics such as fentanyl, sufentanil, butorphanol etc (col 6).

Ansel et al teaches a preparation of pharmaceutical and drug dosage forms in the form of powders or granules having various particle sizes such as coarse, fine, very fine etc. and number of methods to determine the particle size and their distribution

(pages 164-178). Ansel also teaches that there is a substantial difference in the size, morphology and size distribution of particles depending on the substance in use that can influence a variety of important factors in the delivery of drugs. Among those factors, the dissolution rate of particles is affected by micronization of drug, which can increase the rate of dissolution and its bioavailability, uniformity of distribution of drug, absorption of drugs etc. (page 170). Ansel also provides various mathematical ways to ensure the right geometry of particle size is obtained so as to achieve the desired rate.

Thus, multiparticulate modified release composition that delivers an active ingredient in a pulsed manner of **Devane et al** and preparation of pharmaceutical dosage forms in various sizes and their influence in delivery of drugs of Ansel et al anticipates instant claims.

It would have been obvious to one of ordinary skill in the art to apply metal implant or device of **Davidson et al (US Pat# 6,238,491) and Llanos et al (Pub. No. US 2002/0165608)** since Devane el al and Ansel el al teaches the multiparticulate modified release composition and preparation of pharmaceutical dosage forms.

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sudhakar Katakam whose telephone number is 571-272-9929. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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